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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,820	01/28/2002	Jonathan S. Bogan	0399.2025-002	2441
21005	7590	04/06/2004	EXAMINER	
HAMILTON, BROOK, SMITH & REYNOLDS, P.C. 530 VIRGINIA ROAD P.O. BOX 9133 CONCORD, MA 01742-9133			LEFFERS JR, GERALD G	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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**Office Action Summary****Application No.**

10/058,820

**Applicant(s)**

BOGAN ET AL.

**Examiner**

Gerald G Leffers Jr., PhD

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --****Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 January 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) 22-24 and 32-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21, 25-31 and 54-57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 1/28/02 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3/21/03, 10/04/02, 6/24/03
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's election without traverse of Group I (claims 1-21, 25-31 and 54-57) in the response filed 1/12/2004 is acknowledged. Claims 22-24 and 32-53 are withdrawn from consideration as being directed to nonelected inventions.

#### ***Information Disclosure Statements***

Receipt is acknowledged of information disclosure statements (IDS) filed 10/04/2002, 3/31/2003 and 6/24/2003. The corresponding PTO Form 1449's have been signed and initialed, and have been mailed along with the instant action.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21, 25-31 and 54-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 15, 25 and 54 all recite the limitation of a protein that is "involved in" GLUT4 trafficking and are directed to methods of identifying such proteins. Upon reading the specification, it appears that expression of the candidate proteins is required in order to practice the claimed invention. In no instance, however, is there an explicit linkage between the expression of the candidate protein in the host cell the alteration in Glut-4 trafficking at the cell surface that is observed. This element appears to be critical to practicing the claimed invention

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and establishing that the candidate protein is actually “involved in” GLUT4 trafficking. The lack of this critical linkage in the recited methods steps makes it unclear as to what is required to meet the end result of the claims stated in the preamble of the rejected claims. It would be remedial to amend the claim language to clearly indicate the candidate proteins are expressed and that their expression is linked to any observed changes in GLUT4 at the cell surface.

It is unclear, as claims 1, 15 and 54 are currently written, whether one must know *a priori* that the expression library *necessarily* comprises DNA encoding a protein involved with GLUT4 trafficking or whether the claims further encompass embodiments where one simply screens any expression library for DNAs encoding a protein that alters GLUT4 concentrations at the cell surface (i.e. a method of enrichment for cells comprising a particular type of DNA where the DNA is known to be present versus a screening method where the content of the library is unknown). It would be remedial to amend the claim language to clearly indicate whether the latter embodiment is encompassed by the claims or not.

Claims 1, 15, 25 and 54 each recite the limitation of “altered proportion of GLUT4 at the cell surface” or “altered GLUT4 trafficking” without making it clear what the reference is for comparison. For example, in some of the claims it is recited that the differences are observed following insulin stimulation of the cells. It is unclear, however, as the claims are currently written whether the comparison is between cells before and after insulin treatment, or between cells not expressing the protein and cells that do express the protein. It would be remedial to amend the claim language to clearly delineate between the two possibilities.

Claims 3, 15, and 25 each recite the limitation that the test population of cells is stimulated with insulin. It is unclear as the claims are written whether practicing the claimed

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methods will necessarily recapitulate the preamble of the claims. For example, it is known in the art that insulin stimulates release of GLUT4 from compartments within a cell to the cell surface. Therefore, for claims where there is a limitation that the cells are stimulated with insulin, it is unclear whether practicing the recited steps will necessarily identify a cell comprising a DNA encoding a protein that is involved with GLUT4 trafficking if the cells are already going to demonstrate a change in the concentration of a GLUT4 protein on the cell surface.

Claim 8 is vague and indefinite in that there is no clear and positive prior antecedent basis for the phrase "wherein the cells were cultured in media with high amino acid content". At which stage in the method of claim does the phrase apply as there are several culturing steps present in claim 6, upon which claim 8 depends?

Claims 12-14 are vague and indefinite in that there is no clear and positive prior antecedent basis for the phrase "The expression library prepared in the method". There are several different libraries prepared in the claims upon which claims 12-14 are dependent.

Claim 25 is vague and indefinite in that the meets and bounds of the phrase "enriched for DNA encoding a protein involved in GLUT4 trafficking" are unclear. To what degree and compared to what is the expression library "enriched"?

Claim 56 is vague and indefinite in that the metes and bounds of the phrase "desired level of enrichment" are unclear. The term "desired level" is a highly subjective term and is open to interpretation by each prospective artisan. It would be remedial to amend the claim language to include a definite measure by which one attains a "desired level" of enrichment for cells encoding a protein involved with GLUT4 trafficking.

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***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (571) 272-0772. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Gerald G Leffers Jr., PhD  
Primary Examiner  
Art Unit 1636

**GERRY LEFFERS  
PRIMARY EXAMINER**